Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

REMARKS

In the Office Action mailed 08/01/2006, the Examiner objected to claims 24, 25,
29 and 36 due to informalities; rejected claims 1-5, 7-10, 12-18, 23, 25, 26, 28-29,
32-33 and 36 under 35 U.S.C. s. 102(b) as anticipated by John '467; rejected claim
6 under 35 U.S.C. s. 103(a) as unpatentable over John '467 in view of Tarassenko
'857; rejected claim 11 under 35 U.S.C. s. 103(a) as unpatentable over John '467
in view of Viertio-Oja '291; rejected claims 19, 22 and 24 under 35 U.S.C. s.
103(a) as unpatentable over John '467 in view of Lesser '865; rejected claim 20
under 35 U.S.C. s. 103(a) as unpatentable over John '467 in view of Tarassenko
'857 and further in view of Lesser '685; and rejected claims 30-31 under 35
U.S.C. s. 103(a) as unpatentable over John '467 in view of Lewis '611. Claims 21
and 27 were apparently rejected but no grounds for rejection were stated. Claims
3, 10, 19, 20, 24, 25, 28, 29, and 34-36 have been canceled. Claims 1, 4, 6, 16-18,
21-23, 26, 27, 32, and 33 have been amended. New claims 37-42 have been
added.

Claim Objections

Claims 24, 25, 29 and 36 were objected to because of various informalities. The
Applicants thank the Examiner for her helpful comments and suggestions, and
submit that the Claims as amended overcome the Examiner's objection.

Page 18 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

Claim Rejections

Claims 1-2, 4-5, 7-9, 12-18, 23, 26, 32-33 and 36 were rejected under 35 U.S.C. 102(b) as being anticipated by John (U.S. Patent No. 6,067,467). The Applicants submit that the Claims as currently amended are not anticipated by John '467.

With respect to Claims 1-2, 4-5, 7-9, 12-18, 23 and 26, John'467 does not teach nor disclose either the steps of <u>selecting a wavelet transformation function which, when applied to said at least one reference signal yields a set of coefficients</u>, the step of <u>applying said wavelet transformation...to ...distinguish the distinct CNS state(s) corresponding to one or more ...of the reference signals</u>; or <u>applying said wavelet transformation to [an] ...observed signal</u>. John'467 instead teaches the use of a FFT (Fast Fourier Transform) to analyze both a reference signal and an observed signal. In John'467, these signals after statistical processing are then compared to determine differences between the reference state and the observed states. FFT is used where signal characteristics do not change or vary significantly over time. FFT discards time information.

Wavelet analysis on the other hand preserves both time and frequency information, and therefore is commonly used to capture events, for example such as in epilepsy. Epilepsy is known for giving short transient signals with a wide spectrum of frequencies that characterize these events. However, wavelet analysis to capture events such as in epilepsy is entirely different from the present

Page 19 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

application to analyze subtle or gradual changes in CNS state. Clearly John'467
used FFT and not wavelets because of the characteristics of the analysis being
performed. John'467 assumes by using FFT that both the reference signals and
observed signals do not change, or do not change significantly, within the
analyzed epoch. Because of the type of application being performed, this is a
reasonable assumption by John'467 and it would be counterintuitive to use
wavelet analysis in John's application.

The Applicants, however, used wavelet analysis in part based on the decreased
computational demands of wavelet transforms, which results in decreased
computational demands, as well as faster and improved analysis (real time). FFT,
on the one hand, requires for a signal of n points, a number of computing
operations that is proportional to $n \times \log_2(n)$. Wavelet transform, on the other
hand, requires for a signal of n points, a number of computing operations that is
proportional to n. Therefore, the number of computing operations when using FFT
increases by approximately one order of magnitude. This has a tendency to slow
down the analysis resulting in a very poor ability to respond to changes in the
patient's CNS state thereby defeating the purpose of the analysis in the first place.

The Applicants found unexpectedly by using wavelet analysis that not only could
they take advantage of the computing efficiency of wavelet analysis, but that by
appropriately adjusting such analysis they could detect subtle or gradual changes
in CNS state with similar accuracy to those being performed traditionally by FFT.

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

However, the use of wavelet transform has allowed the Applicants to increase dramatically the update rate of the value(s) representative of the patients' CNS state.

In addition with respect to Claim 4, John'467 does not teach or disclose a method wherein the <u>reference signal is only obtained from said one or more reference subject or subjects who are not the same individual as said observed subject.</u> Instead, John'467 teaches that the reference signal is at all times at least in part obtained directly from the observed subject (self-norm). The Applicants direct the Examiner's attention to the following: John'467 discloses that the reference subject or subjects may include persons other than the patient (column 3, lines 57-58). However, it is important to understand that <u>John'467 still requires the self-norm obtained from the monitored patient</u> as reiterated throughout the patent (column 2, lines 53-67; column 3, lines 34-38; I. PRE-OPERATIVE: column 4, lines 45-61; II. INTER-OPERATIVE: column 7, lines 4-7; III. INTRA-OPERATIVE: column 8, lines 33-34, column 9, lines 20-21, column 11, lines 10-15; IV. THE RECOVERY ROOM/ICU: column 14, lines 64-65). Furthermore, John'467 argues (with respect to the U.S. patent no. 5,010,891) that "the comparison of patients with a normal group, in itself, is not believed to provide reliable information in the surgical context of determining if a patient will be sufficiently anesthetized" (column 2, lines 34-38). As a result, reference data obtained from a normative database of subjects (i.e., other than the monitored patient), when used by John'467, come <u>only as a supplement to the self-norm data.</u>

Page 21 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

and are neither necessary nor (more importantly) sufficient. However, in the current invention, the Applicants have found from their investigations that <u>it is sufficient to use reference data sets that are only obtained from a group of subjects or patients other than the monitored subject, thereby making the invention more practical and less prone to errors.</u>

In addition with respect to Claim 12, John'467 does not teach or disclose the claimed method <u>being used to measure neurological activity in said subject to ascertain titration and dosage profiles of neurologic and psychoactive compounds and medicaments.</u> Instead, in Column 15, lines 37-41 John'467 indicates that only "after a database has been established, which comprises both the data from the operation <u>and subsequent patient outcomes</u>" can the method of John'467 be used to play a greater role in suggesting the proper level of anesthesia. The present invention teaches the use of its method to determine titration and dosage profiles immediately without creating a database.

In addition with respect to Claim 13, John does not teach nor disclose the claimed method <u>being used to measure neurological activity in said subject to detect and ascertain the level of brain ischemia.</u> The Examiner references Column 1, lines 53-57 in the background of the invention, which clearly does not suggest using the method of John'467 to detect and ascertain the level of brain ischemia. John'467 only suggests that one of the reasons to properly administer general anesthetics is to prevent low blood pressures which could result in hypoxia. John'467 does not

Page 22 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

suggest directly using their method to detect and ascertain levels of brain

ischemia.

In addition with respect to Claim 17, John'467 does not teach nor disclose the

claimed method wherein <u>at least two reference signals are acquired, and said</u>

<u>reference signals correspond to distinct CNS states which are two extreme states</u>.

While John'467 teaches acquiring reference signals from different CNS states, he

does not teach nor suggest using two distinct references to compare with the

observed signal let alone comparing the observed signal with references from two

extreme states. Instead, John'467 promotes comparing a reference signal which is

at a similar CNS state with an observed signal at that same CNS state (i.e., within

a "reference band") to determine whether there is a significant enough deviation

from the desired "plane of anesthesia". Column 2, lines 59-67.

In addition with respect to Claim 18, John'467 does not teach nor disclose the

claimed method <u>wherein said extreme states are fully conscious and substantially</u>

<u>no brain activity</u>. Again John'467 never teaches or suggests using two distinct

reference signals corresponding to two different CNS states to compare with the

observed signal. John'467 promotes comparing a reference signal which is at a

similar CNS state with an observed signal at that same CNS state (i.e., within a

"reference band") to determine whether there is a significant enough deviation

from the desired "plane of anesthesia". Column 2, lines 59-67.

<div align="center">Page 23 of 37</div>

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

With respect to Claim 32, John '467 does not teach or disclose a system

comprising a digital signal processor for applying a <u>wavelet transformation</u>

<u>function and said statistical function to said observed signal to produce an</u>

<u>observed data set</u>; then comparing the observed data set [analyzed with the

wavelet transformation function] to one or more said reference data sets; and

computing a numerical value or values representative of said level of depression

of the CNS of said subject which results from said comparison.

John '467 instead teaches the use of a digital signal processor using FFT (Fast

Fourier Transform) to analyze both a reference signal and an observed signal. In

John '467, these signals after statistical processing are then compared to determine

differences between the reference state and the observed states. FFT is used where

signal characteristics do not change or vary significantly over time. FFT discards

time information.

Wavelet analysis on the other hand preserves both time and frequency

information, and therefore is commonly used to capture events, for example such

as in epilepsy. Epilepsy is known for giving short transient signals with a wide

spectrum of frequencies that characterize these events. However, wavelet analysis

to capture events such as in epilepsy is entirely different from the present

application to analyze subtle or gradual changes in CNS state. Clearly John'467

used FFT and not wavelets because of the characteristics of the analysis being

performed. John'467 assumes by using FFT that both the reference signals and

Page 24 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

observed signals do not change, or do not change significantly, within the analyzed epoch. Because of the type of application being performed, this again is a reasonable assumption by John'467 and it would be counterintuitive to use wavelet analysis.

As noted above, the Applicants, however, used wavelet analysis in part based on the decreased computational demands of wavelet transforms, which results in decreased computational demands, as well as faster and improved analysis (real time). FFT, on the one hand, requires for a signal of n points, a number of computing operations that is proportional to $n \times \log_2(n)$. Wavelet transform, on the other hand, requires for a signal of n points, a number of computing operations that is proportional to n. Therefore, the number of computing operations when using FFT increases by approximately one order of magnitude. This has a tendency to slow down the analysis resulting in a very poor ability to respond to changes in the patient's CNS state thereby defeating the purpose of the analysis in the first place.

The Applicants found unexpectedly by using wavelet analysis that not only could they take advantage of the computing efficiency of wavelet analysis, but that by appropriately adjusting such analysis they could detect subtle or gradual changes in CNS state with similar accuracy to those being performed traditionally by FFT. However, the use of wavelet transform has allowed the Applicants to increase dramatically the update rate of the value(s) representative of the patients' CNS

Page 25 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

state.

With respect to Claim 33, in addition to the comments with respect to Claim 32, it is unclear whether John'467 uses embedded language or software and therefore it is not inherent based on John'467 to use a computer program.

Given the amendments to the Claims, and the reasons set forth in this response, the Applicants submit that it is clear that the amended claims are not anticipated by John '467, and respectfully request that the Examiner withdraw the rejection under 35 U.S.C. s. 102(b) as anticipated by John '467.

Claim 1 as amended incorporates the limitations of claim 19, now cancelled, which the Examiner had rejected under 35 U.S.C. s. 103(a) as unpatentable over John '467 in view of Lesser '865. It is further submitted that the amended claims would not be obvious over John '467 in view of Lesser '865 for the following reasons.

The Applicants point out to the Examiner that Lesser '685 is not a valid prior art reference with respect to new matter in Lesser '685, which has an April 15, 2003 filing date. The Applicants' priority date is July 12, 2002. It is assumed that the Examiner is basing the objection on the subject matter of Lesser application no. 09/691,051 of which '685 was a continuation-in-part, now U.S. Patent 6,882,881 ('881). For the following reasons, it is further submitted that the amended claims would not be obvious over John '467 in view of Lesser '881.

Page 26 of 37

The Applicants remind the Examiner that to establish a *prima facie* case of
obviousness it is not enough for the Examiner to present references that contain the
assorted features of the Applicants' invention, but rather it is the Examiner's
burden to show why it would appear that the references would have been
combined. To do so the Examiner must provide: 1) one or more references, 2) that
were available to the inventor, 3) that teach, 4) a suggestion to combine or modify
the references, and 5) the combination or modification of which would appear to be
sufficient to have made the claimed invention obvious to one of ordinary skill in
the art.

The Applicants further submit that the Examiner has not given any reason,
suggestion, or motivation in the references, or from the references cited as a whole
for the person of ordinary skill to have combined or modified the references.
"When a rejection depends on a combination of prior art references, there must be
some teaching, suggestion, or motivation to combine the references." *In re Rouffet,*
149 F.3d 1350, 1355, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998). Furthermore,
"rejecting patents solely by finding prior art corollaries for the claimed elements
would permit an examiner to use the claimed invention as a blueprint for piecing
together elements in the prior art to defeat the patentability of the claimed
invention." *Sensonics, Inc. v. Aerosonic Corp.,* 81 F.3d 1566, 1570, 38 U.S.P.Q.2D
(BNA)1554 (Fed. Cir. 1996). Therefore in order to prevent the use of hindsight
based on the invention the examiner must show reasons that the skilled artisan,
confronted with the same problem as the inventor and with no known knowledge

Page 27 of 37

of the claimed invention, would select the elements from the cited prior art references for combination. *In re Rouffet*, 149 F.3d 1350, 1355, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998).

The court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. *In re Rouffet*, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d (BNA) 1453 (Fed. Cir. 1998).

Lesser '881 in Column 7, lines 62-67 actually teaches away from the method of the present invention by suggesting that "wavelet-crosscorrelation...be used to assess brain activity...to both predict or detect the likely occurrence of <u>unwanted</u> brain activity..." The method of the present invention teaches to use wavelet to analyze normal brain activity rather than unwanted activity such as seizures. Furthermore, Lesser '881 is not used to measure the level of depression of the CNS of the subject, but rather is used for event-detection.

Lesser '881 clearly state that their invention is for treating disorders including brain disorders (column 1, lines 12-21; column 8, lines 66-67 and column 9, line 1). They assess brain activity using wavelet-cross correlation to predict or detect unwanted brain activity and to determine when best to administer a treatment, such as stimulation, so as to prevent or abort the unwanted activity (column 7, 62-67). The invention is directed towards electrical stimulation using implanted electrodes and for predicting and treating seizures (column 11, lines 13-19). The inventors

teach the use of wavelet-crosscorrelation that they developed "for analyzing dynamics of epileptiform discharges" (column 11, 35-38), <u>which are events well localized in time</u>. It is therefore evident to use wavelets in such applications, since wavelets are particularly well suited for event-detection due to their time-frequency localization properties. Moreover, note that wavelets are commonly used for detection of transient, well-localized events. In Lesser, the subject is being observed to detect brain disorders such as epilepsy, etc and to administer brain stimulation upon those events. Epilepsy is known for giving short transient signals with a wide spectrum of frequencies that characterize these events. Wavelet analysis to capture events such as in epilepsy is entirely different from the present application to analyze subtle or gradual changes in CNS state.

In re Eynde, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973) states that "The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men [and women] and are not amenable to the taking of [judicial] notice." The Examiner stated in her rejections that it would have been <u>obvious to a person of ordinary skill in the art</u> at the time the invention to combine the references. MPEP 2144.03 B. states that the "holding ...[of] general conclusions concerning what is "basic knowledge"...to one of ordinary skill in the art without specific <u>factual</u> findings and some concrete evidence in the record to support these findings will not support an obviousness rejection." Section MPEP 2144.03 goes on further to say "The examiner must point to some concrete evidence in the record in support of these findings to support the substantial evidence test....<u>If the Examiner is relying on personal knowledge to</u>

support the finding of what is known in the art, the examiner must provide an
affidavit or declaration setting forth specific factual statements and explanation to
support the finding." The Applicants therefore request that if such suggestion or
incentive is in the references, that the Examiner particularly point out the relevant
sections of those references, particularly given the large difference in the types of
devices described by these two references and their applications. If the Examiner
is alleging that a person of ordinary skill would have been motivated to combine
such references such as she appears to be doing in the Office Action, such
knowledge must be personal to the Examiner, and therefore the Applicants
respectfully request that the Examiner submit an affidavit detailing as specifically
as possible such motivation (see 37 CFR §1.104 (d)(2)).

Given the amendments to the Claims and the reasons set forth in this response, the
Applicants respectfully request that the Examiner withdraw the obviousness
rejection based on a combination of John and Lesser.

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over John '467
in view of Tarassenko (U.S. Patent No. 7,031,857). Claim 6 depends from claim
1, which is patentable for the reasons noted above. The Applicants repeat their
comments with respect to Claim 1. Being dependent from a patentable claim,
Claim 6 is therefore also patentable. Per MPEP 2143.03, if an independent claim is
nonobvious under 35 U.S.C. 103, then any claim depending therefrom is
nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). The
Applicants further submit that the Claim as currently amended would not be

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

obvious over John '467 in view of Tarrassenko'857 for the following reasons.
Tarrassenko'857 does not teach or disclose the application of a statistical function
being a probability density function which is applied to the observed and reference
signals at different times, as claimed.

Tarassenko'857 provides an apparatus for displaying a graphical representation of
a patient's condition as measured from a variety of sources in a way which allows
the patient's overall condition to be recognized easily. In that respect,
Tarassenko'857 teaches the application of a probability density function to n
different observed physiological measurements or signals, where n > 3. In
addition, a probability density function is applied at the same time to both the
observed and prototype signals to determine the distance between the observed
multi-dimensional data point and the predefined normal prototypes representing a
normal condition for the patient. Tarrasenko'857 achieves this by using a suitably
trained artificial neural network. Column 1, lines 10-14, Column 2, lines 13-33,
Column 9, lines 26-29, Column 9, line 66 through Col. 10, line 21.

Unlike Tarrassenko'857, the Applicants apply a probability density function to a
single physiological measurement, [an] observed signal [representing measured
brain activity of a subject] to produce an observed data set. In a separate step, and
at an earlier time, the Applicants apply a probability density function to said at
least one reference signal to produce one or more reference data sets which
distinguish the distinct CNS state(s). In yet another step, the produced observed

Page 31 of 37

and reference data sets are compared to evaluate [the] level of depression of the CNS of ... [monitored] subject. The process in Tarassenko'857 is not similar nor does it relate to the process in John'467 or with the method described in the present invention.

The Applicants submit further that Tarrassenko'857 is not analogous art because it relates rather to the display of a patient's physiological parameters. The Applicants further submit that the Examiner has not given any reason, suggestion, or motivation in the references, or from the references cited as a whole for the person of ordinary skill to have combined or modified the references. The comments above concerning the Lesser reference are repeated with respect to Tarrassenko'857. Given the amendments to the Claims and the reasons set forth in this response, the Applicants respectfully request that the Examiner withdraw this rejection.

Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over John'467 in view of Viertio-Oja (U.S. Patent No. 6,631,291). Claim 11 depends from claim 1, which is patentable for the reasons noted above. The Applicants repeat their comments with respect to Claim 1. Being dependent from a patentable claim, Claim 11 is therefore also patentable. The Applicants further submit that the Claim as currently amended would not be obvious over John '467 in view of Vierto-Oja'291 for the following reasons. Vierto-Oja'291 uses their method of entropy to monitor brain signals to establish pharmacodynamic and pharmacokinetic models of drug effects. Entropy quantifies the randomness of a

Page 32 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

signal. FFT quantifies frequency content of a signal. Wavelets quantify both time
and frequency content of a signal. There is no correlation between entropy and
FFT or Wavelets.

The Applicants further submit that the Examiner has not given any reason,
suggestion, or motivation in the references, or from the references cited as a whole
for the person of ordinary skill to have combined or modified the references. The
comments above concerning the Lesser reference are repeated with respect to
Vierto-Oja'291. Given the amendments to the Claims and the reasons set forth in
this response, the Applicants respectfully request that the Examiner withdraw this
rejection

Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over
John'467 in view of Lesser (U.S. Patent Application No. 2003/0171685). The
Applicants submit that the Claim as currently amended would not be obvious over
John '467 in view of Lesser for the following reasons. Claim 22 depends from
Claim 1, which is patentable over John in view of Lesser for the reasons noted
above. The Applicants repeat their comments with respect to Claim 1. Being
dependent from a patentable claim, Claim 22 is therefore also patentable. In
addition, and as noted above, Lesser '881 in Column 7, lines 62-67 actually
teaches away from the method of the present invention by suggesting that
"wavelet-crosscorrelation...be used to assess brain activity...to both predict or
detect the likely occurrence of <u>unwanted</u> brain activity..." The method of the
present invention, with respect to Claim 22, teaches to use any transform with

joint time and frequency localization properties to analyze normal brain activity

rather than unwanted activity such as seizures. Furthermore, Lesser '881 is not

used to measure the level of depression of the CNS of the subject, but rather is

used for event-detection.

Lesser '881 clearly state that their invention is for treating disorders including

brain disorders (column 1, lines 12-21; column 8, lines 66-67 and column 9, line

1). They assess brain activity using wavelet-cross correlation to predict or detect

unwanted brain activity and to determine when best to administer a treatment, such

as stimulation, so as to prevent or abort the unwanted activity (column 7, 62-67).

The invention is directed towards electrical stimulation using implanted electrodes

and for predicting and treating seizures (column 11, lines 13-19). The inventors

teach the use of wavelet-crosscorrelation that they developed "for analyzing

dynamics of epileptiform discharges" (column 11, 35-38), which are events well

localized in time. It is therefore evident to use wavelets in such applications, since

wavelets are particularly well suited for event-detection due to their joint time-

frequency localization properties. However, joint time-frequency analysis to

capture events such as in epilepsy is entirely different from the present application

to analyze subtle or gradual changes in CNS state. Given the amendments to the

Claims and the reasons set forth in this response, therefore, the Applicants

respectfully request that the Examiner withdraw this rejection.

Claims 30 and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

John'467 in view of Lewis (U.S. Patent No. 5,762,611). The Applicants submit

that the Claims as currently amended are not obvious over John'467 in view of

Lewis. Claims 30 and 31 depend from Claim 1, which is patentable for the

reasons noted above. The Applicants repeat their comments with respect to

Claim 1. Being dependent from a patentable claim, Claims 30 and 31 are therefore

also patentable. Further, Lewis' 611 states, column 8, lines 44-48: "These

publications reported on data using a single channel neuron-magnetometer,

however, other multi-channel neuron-magnetometer systems, such as the BTI

model 605, for the recording of EF data over more channels and larger number of

brain regions could be used."

EEG device does not fall under the scope of neuro-magnetometers, which are

complex devices that record magnetoencephalography. Applicants do not need

such a complex device to record their signal. Moreover, Lewis'611 teaches a

method for analyzing the brain waves, stating that the brain waves, in the context

of his invention, imply <u>evoked or event-related potentials</u> (column 1, lines 55-58).

The use of evoked potentials is entirely different analysis from the analysis of

spontaneous brain activity. In addition, such analysis is less practical since it

requires the delivery and analysis of appropriate stimuli and associated devices.

The current invention does not require evoked potentials and thus avoids additional

and unnecessary complexity.

The Applicants further submit that the Examiner has not given any reason,

suggestion, or motivation in the references, or from the references cited as a whole

<center>Page 35 of 37</center>

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

for the person of ordinary skill to have combined or modified the references. The

comments above concerning the Lesser reference are repeated with respect to

Lewis. Given the amendments to the Claims and the reasons set forth in this

response, the Applicants respectfully request that the Examiner withdraw this

rejection.

Conclusion:

It is submitted therefore that the amended claims are allowable, and issuance of a

Notice of Allowance is therefore respectfully requested.

Respectfully submitted,

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Page 36 of 37

Appl. No. 10/616,997
Amendment in response to
Office Action mailed 08/01/2006

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Page 37 of 37